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(54) ISOTACTIC POLYPROPYLENE SURGICAL SUTURES

- (71) We, AMERICAN CYANAMID COMPANY, a Corporation organized and existing under the laws of the State of Maine, United States of America, of Berdan Avenue, Township of Wayne, State of New Jersey, United States of America, do hereby declare the invention for which we pray that a patent may be granted to us, and the method by which it is to be performed, to be particularly described in and by the following statement:-
- This invention relates to a polypropylene suture.
- Surgical sutures are divided into two broad classes, absorbable sutures such as catgut or polyglycolic acid which are absorbed in the human body, and non-absorbable sutures which remain essentially unchanged by action of the body tissues and fluids. Such non-absorbable sutures are frequently removed after the repaired tissues are healed. However, there are also many occasions, such as in heart repair or cardiovascular surgery, where tissue healing never becomes self-supportive, and the sutures must provide continual non-failing support. Among the several important characteristics of sutures used in such applications are (a) resistance to "creep" or longitudinal elongation under continued stress, possibly permitting failure of a repaired section, and (b) the ability of the suture to withstand long-time continued flexing such as would occur in a vessel such as the aorta due to continuous pulsation resulting from blood flow; or in heart repair, due to continuous flexing due to heart beat. Although flex and creep resistance are inherent in well-made braided sutures, there are a number of reasons why surgeons prefer to use a monofilament suture rather than a braid suture in many of these applications.
- Sutures of high density linear polyethylene have been used to a large degree as general non-absorbable sutures. However, it has been reported that application of these sutures in areas such as heart repair and cardiovascular surgery have been noted to have failed, assumably due to a poor long time flex life. Polypropylene sutures now being marketed are also found to have creep and flex resistance characteristics which are not as satisfactory as would be desired.
- In accordance with the present invention there is provided a substantially isotactic polypropylene (as hereinafter defined) suture having a diameter of from 0.0025 to 0.030 inch and a denier of from 30 to 3000, said suture having the following characteristics:
- | | |
|---------------------------------|---|
| Tensile Strength at Break - gpd | 4.3-7.5 |
| Knot Strength - gpd | 3.0-5.0 |
| Percent Elongation to Break | 20.0-30.0 |
| Young's Modulus - psi | 5.4×10^5 - 9.5×10^5
or 50-80 gpd |

Flexural Fatigue Resistant (F)
(Cycles to Break) approximately
equal to that given by the formula:
 $F = 1.251 \times 10^8 \times D^{-1.77}$
where D = suture denier
Static Creep - % Elongation

<8.0

Polypropylene sutures in accordance with the present invention exhibit superior long range flex life and an improve creep resistance, which render them desirable for wound repair. These sutures may be prepared by a method which comprises: (a) extruding a substantially isotactic polypropylene (as hereinafter defined) at a temperature ranging from 425°F to 550°F into a filament; (b) liquid quenching said filament at a temperature ranging from 125°F to 175°F with a simultaneous drawing thereof of 1.0 to 5.0X; (c) passing said quenched and drawn filament through a heating and drawing zone at a temperature of approximately 205°F to impart thereto a 5.0 to an 8.0X draw; (d) and passing said heated and drawn filament through a second heating and drawing zone at a temperature ranging from 300°F to 450°F to impart thereto a final draw of from 0.95 to 1.6X.

In the preferred embodiment of the invention, substantially isotactic polypropylene having a weight average molecular weight of about 350,000, although higher or lower molecular weight material may be used, is extruded, utilizing a conventional extruder, at temperatures of from 425°F. to 550°F., and is then liquid quenched at 125°F. to 175°F. The formed filaments are then preliminarily drawn off from 1.0X to 5.0X by a godet assembly. From the first godet, the yarn is drawn again by a second godet through a six-foot hot water draw tank at about 205°F. to give from a 5.0X to 8.0X draw ratio. This twice-drawn yarn is then drawn for a third time through a six-foot infrared chamber heated to 300-450°F. at a final draw of from 0.95X to 1.6X. The filaments are then collected and cut to the required length. Filaments made in this manner have a flex life and creep resistance far superior to polyethylene and to presently commercially available polypropylene sutures. By "substantially isotactic" used herein is meant that the polypropylene may contain up to 15% atactic configuration but is preferably as completely isotactic as possible.

More specifically, isotactic polypropylene pellets, either natural or colored, such as with copper phthalocyanine blue, are placed into the feed hopper of a conventional polymer extruder and flow by gravity into the water-cooled extruder hopper throat where they are propelled through the extruder barrel by the extruder screw which is driven by a variable speed drive unit. The temperature of the extruder barrel is controlled at about 425-550°F. by three electrically heated zone blocks surrounding the barrel, with the controller units mounted in a panel board. From the extruder, the molten polymer flows under pressure into the spin head which is heated and controlled by a heater-controller unit. The flow of the molten polymer is regulated by a precision metering pump driven by a variable speed drive. The pump forces precisely measured quantities of melt continuously through a multi-hole spin jet. The molten streams pass through a temperature controlled liquid quench bath which is at 125-175°F. and are pulled over two submerged rollers and a guide-wiper unit by a godet station consisting of skewed godets to thereby draw the filaments from 1.0X to 5.0X and subsequently solidify them. They then pass through an electrically heated and controlled six-foot hot water draw tank to a second set of godets rotating at a faster surface speed than the first godet unit. This faster speed rate imparts a stretch or draw of from 5.0X to 8.0X to the filaments thus partially orienting them and causing a marked decrease in diameter and increase in strength. From the second godet assembly, the filaments are drawn through a heated infrared chamber which is at a temperature of from 300-450°F. by a third godet assembly to give a draw ratio of from 0.95-1.6X.

The filaments are then separated and wound onto spools in a manner known to those skilled in the art, i.e., the individual filaments are separated through guides, passed over rollers, tension arms and reciprocating traverse guides, and are ultimately wound on spools. These spools are stored for further processing such as cutting, needling, packaging, sterilizing, etc. in the conventional manner.

As mentioned above, the substantially isotactic polypropylene filament, produced as described above, can be prepared in its natural color or can be colored by mechanically blending the pellets of polymer charged to the extruder with a pigment such as copper phthalocyanine blue in quantities of about 1% or less. Plasticizers and stabilizers may also be incorporated for purposes and in a manner known to those skilled in the art.

Single strand or monofilaments are preferred as the sutures of the instant invention. However, multi-filaments can also be used in a twisted or braided construction as is known in the art. The sutures may be of round, oval, flat, square, triangular, or other configurations, the specific shape thereof not forming any part of the instant invention. The

invention also provides a surgical suture package comprising a sterile enclosure and therein a sterile polypropylene suture of the present invention.

The suture may be presented attached to a surgical needle with both the suture and needle being sterile. Thus, for example, the sutures may be dry-packed in glass tubes or plastic packages since they are relatively stable. However, a conditioning fluid may be used so as to prevent needle rusting and ensure sterility. The packaged sutures may be sterilized with ethylene oxide or other sterilizing gas and sealed, or the package may be sealed first and then sterilized by heat or radiation.

As mentioned above, sutures of the instant invention can have an exceptionally long-range flex life, and a substantially improved creep resistance when compared to those polypropylene sutures currently commercially available. These sutures, therefore, possess a longer useful suture life in living bodies due to their superior resistance to creep and flexion resulting from body movement, e.g. pulsation of blood vessels, etc. They also retain those other attributes of known polypropylene sutures such as strength, non-absorption, lack of toxicity, etc. which are required of a permanent or semipermanent surgical suture.

As mentioned briefly above, the unique properties of the sutures of the present invention are represented primarily by their static creep and fatigue or flex life values. More precisely, our novel sutures comprise a substantially isotactic polypropylene (as hereinbefore defined), the diameter of which ranges from 0.0025 to 0.030 inch, having a denier of 30 to 3000; and having the following characteristics:

Tensile Strength at Break	4.3-7.5 gpd
Knot Strength	3.0-5.0 gpd
Percent Elongation to Break	20-30
Young's Modulus	5.4-9.5 $\times 10^5$ psi or 50-80 gpd

Flexural Fatigue Resistance (F)
approximately equal to that
given by the formula:

$$F = 1.251 \times 10^8 \times D^{-1.77}$$

wherein D = denier

Static Creep - % Elongation < 8.0

The following test methods are used to measure the physical characteristics of the present sutures.

Tensile Strength and Elongation Testing

The Tensile Strength at Break and Percent Elongation to Break are run on an "Instron" (registered Trade Mark) Table Model constant rate of extension tensile tester. This instrument is manufactured by the Instron Corporation of Canton, Massachusetts.

The test method is ASTM D-2256 66T (see 1971 book, part 24), which describes the measurement of both tensile strength at break and elongation to break. In order to eliminate excessive jaw breaks a yarn and cord style clamp is used. The 20 seconds to break is approximated by using a 10" gauge length and 10"/min. cross head speed. The cell size used is that which is approximate to the suture size under test.

Static Creep

The static creep test is designed to test the filament's ability to maintain a constant length while in a body environment under stress. This is accomplished by holding the filament in a tank of water at body temperature (36°C.) under a constant stress. The original length of approximately 5" is marked by two silicone balls, and the increase in length between the balls is noted daily for 5 days.

The applied stress is varied according to the gauge of the suture under test, the loads being approximately 0.625 gpd. The results are reported as % Elongation based on original length.

Modulus (Young's)

The Modulus is also determined using the table model Instron tensile tester equipped with yarn and cord jaws and the appropriate cell. A 10" gauge length and a 10"/min cross head speed are used with a 20"/min chart speed. The Young's Modulus is calculated as the slope of the line CE in the classical Stress-Strain curve.

Knot Strength

Knot strengths are determined on a Scott IP-4 Inclined Plane Tester following the method described in the US Pharmacopeia, Vol. XVII, page 291, using a 127 mm gauge

length and the appropriate carriage-weight combinations and a standard surgeon's knot.

In addition to the physical properties whose measurement is described above, another important physical property of the present sutures is their flexural fatigue resistance. In accordance with this invention, the novel polypropylene sutures are to have a flexural fatigue resistance (F), in terms of cycles to break, approximately equal to that given by the formula:

$$F = 1.251 \times 10^8 \times D^{-1.77}$$

where D is the denier of the suture.

The above formula was derived from measurements of actual flexural fatigue resistance values, in cycles to break, for a series of polypropylene sutures in accordance with the present invention by means of the following test.

Flexural Fatigue Resistance

The purpose of this test is to provide an accelerated means for characterizing the resistance of the filament to continued stress changes and flexing such as would be encountered in a vascular graft or similar operation.

The test is carried out using a Tinius-Olsen MIT folding endurance tester modified to allow variations in cycles/min, angle of flex, and load stress. The tests cited were run at 175 cycles/min, 270° flex and approximately 1.25 gpd load according to the table below. For small suture sizes, a 01010 mil clamp was used and a 0.020 mil clamp for larger sizes. The results are reported as cycles to break or failure.

Table

Suture Size	Test Load (grams)
7/0	44
6/0	75
5/0	175
4/0	300
3/0	500
2/0	850
1/0	1317.5
01	1808
02	2179

The invention is illustrated by the Examples which follow and in which all parts and percentages are by weight unless otherwise specified. The sutures described in the Examples all have diameters within the range of from 0.0025 to 0.030 inch.

Example 1

A size 2/0 polypropylene suture is prepared from isotactic polypropylene with a weight average molecular weight of about 352,000 as follows:

4540 parts of polymer are mixed with 449 parts of a masterbatch containing 5% of copper phthalocyanine blue pigment in polymer and tumbled for 1/2-1 hour in a small drum tumbler. The blend is then transferred to an extruder hopper dryer and dried 15-18 hours at 160°F.

The polymer is then extruded through a standard plasticating screw extruder at 3.3 lbs./hr. The extruder has three barrel zones held at 451°F., 446°F., and 481°F. The heat containing the pump and filter is held at 445°F. and the spin jet at 535°F. The spin jet has 4 holes with 60 mil diameter capillaries. The filaments extruding from the jet pass through an aqueous quench bath held at 150°F. and are pulled away by a godet assembly rotating at 36 fpm to give a primary draw down of about 2.5X. From this godet the yarn is drawn by a second godet rotating at 260.5 fpm through a hot water draw tank six feet long heated to 205°F. to give about a 7.2X draw ratio. The drawn yarn is drawn away from the second godet by a third godet rotating at 250 fpm through a second chamber heated to 400°F. to give an additional draw ratio of 0.96X.

The yarn is then separated into the 4 individual filaments and collected on takeup spools as individual monofilaments. At the end of a collection period the monofilaments are wound off onto appropriate size drums and then cut to give strands of the desired length for suture manufacture. The properties of the resultant filaments are then determined as described above. The results are set forth in Table 1, below.

Example 2

A size 3/0 polypropylene suture is prepared from isotactic polypropylene with a weight average molecular weight of about 352,000 as follows:

4540 parts of polymer are mixed with 449 parts of a masterbatch containing 5% of copper phthalocyanine blue pigment in polymer, and tumbled for 1/2-1 hour in a small drum tumbler. The blend is then transferred to the extruder hopper dryer and dried 15-18 hours at 160°F.

5 The polymer is then extruded through a standard plasticating screw extruder at 3.6 lbs/hr. 5
The extruder has three barrel zones held at 451°F., 446°F., and 481°F. The head containing the pump and filter is held at 445°F. and the spin jet at 535°F. The spin jet has 8 holes with 35 mil diameter capillaries. The filaments extruding from the jet pass through an aqueous quench bath held at 150°F. and are pulled away by a godet assembly rotating at 38 fpm to 10
10 give a primary draw down of about 1.65X. From this godet the yarn is drawn by a second godet rotating at 260.5 fpm through a hot water draw tank six feet long heated to 205°F. to 10
10 give about a 6.9X draw ratio. The drawn yarn is drawn away from the second godet by a third godet rotating at 250 fpm through a second chamber heated to 400°F. to give an additional draw ratio of about 0.96X.

15 The yarn is then separated into the 8 individual filaments and collected on takeup spools 15
as individual monofilaments. At the end of a collection period the monofilaments are wound off onto appropriate size drums and then cut to give strands of the desired length for suture manufacture. The properties of these filaments are set forth in Table I, below.

20 Example 3 20

A size 4/0 polypropylene suture is prepared from isotactic polypropylene with a weight average molecular weight of about 352,000 as follows:

4540 parts of polymer are mixed with 449 parts of masterbatch containing 5% of copper phthalocyanine blue pigment in polymer and tumbled for 1/2-1 hour in a small drum 25
25 tumbler. The blend is then transferred to the extruder hopper dryer and dried 15-18 hours at 160°F.

The polymer is then extruded through a standard plasticating screw extruder at 2.2 lbs/hr. The extruder has three barrel zones held at 451°F., 446°F., and 481°F. the head containing the pump and filter is held at 445°F. and the spin jet at 535°F. The spin jet has 8 holes with 35 mil diameter capillaries. The filaments extruding from the jet pass through an aqueous 30
30 quench bath held at 150°F. and are pulled away by a godet assembly rotating at 38 fpm to give a primary draw down of about 2.5X. From this godet the yarn is drawn by a second godet rotating at 260.5 fpm through a hot water draw tank 6 feet long heated to 205°F. to 30
30 give about a 6.9X draw ratio. The drawn yarn is drawn away from the second godet by a third godet rotating at 250 fpm through a second chamber heated to 450°F. to give an 35
35 additional draw ratio of about 0.96X.

The yarn is then separated into the 8 individual filaments and collected on takeup spools as individual monofilaments. At the end of a collection period the monofilaments are wound off onto 40
40 appropriate size drums and then cut to give strands of the desired length for suture manufacture. The properties of these filaments are determined and set forth in Table I, below.

Example 4

45 A size 5/0 polypropylene suture is prepared from isotactic polypropylene with a weight 45
average molecular weight of about 352,000 as follows:

4540 parts of polymer are mixed with 449 parts of masterbatch containing 5% copper phthalocyanine blue pigment in polymer and tumbled for 1/2-1 hour in a small drum 50
50 tumbler. The blend is then transferred to the extruder hopper dryer and dried 15-18 hours at 160°F.

50 The polymer is then extruded through a standard plasticating screw extruder at 1.3 50
lbs./hr. The extruder has three barrel zones held at 451°F., 446°F., and 481°F. The head containing the pump and filter is held at 445°F. and the spin jet at 535°F. The spin jet has 8 holes with 35 mil diameter capillaries. The filaments extruding from the jet pass through an aqueous quench bath held at 150°F. and are pulled away by a godet assembly rotating at 35 55
55 fpm to give a primary draw down of about 4.3X. From this godet the yarn is drawn by a second godet rotating at 260.5 fpm through a hot water draw tank six feet long heated to 205°F. to give about a 6.9X draw ratio. The drawn yarn is drawn away from the second godet by a third godet rotating at 250 fpm through a second chamber heated to 450°F. to 60
60 give an additional draw ratio of about 0.96X.

The yarn is then separated into the 8 individual filaments and collected on takeup spools as individual monofilaments. At the end of a collection period the monofilaments are wound off onto 60
60 appropriate size drums and then cut to give strands of the desired length for suture manufacture. Table I, below, sets forth the properties of these filaments.

Example 5

A size 6/0 polypropylene suture is prepared from isotactic polypropylene with a weight average molecular weight of about 352,000 as follows:

5 4540 parts of polymer are mixed with 449 parts of masterbatch containing 5% of copper phthalocyanine blue pigment in polymer and tumbled for 1/2-1 hour in a small drum tumbler. The blend is then transferred to the extruder hopper dryer and dried 15-18 hours at 160°F. 5

10 The polymer is then extruded through a standard plasticating screw extruder at 0.5 lbs./hr. The extruder has three barrel zones held at 451°F., 446°F. and 481°F. The spin jet has 8 holes with 20 mil diameter capillaries. The filaments extruding from the jet pass through an aqueous quench bath held at 150°F. and are pulled away by a godet assembly rotating at 30.5 fpm to give a primary draw down of about 2.8X. From this godet the yarn is drawn by a second godet rotating at 185 fpm through a hot water draw tank six feet long heated to 205°F. to give about a 6.1 draw ratio. The drawn yarn is drawn away from the 15 second godet by a third godet rotating at 250 fpm through a second chamber heated to 345°F. to give an additional draw ratio of about 1.35X. 15

20 The yarn is then separated into the 8 individual filaments and collected on takeup spools as individual monofilaments. At the end of a collection period the monofilaments are wound off onto appropriate size drums and then cut to give strands of the desired length for suture manufacture. The properties of these filaments are set forth in Table I, below. 20

Example 6

A size 7/0 polypropylene suture is prepared from isotactic polypropylene with a weight average molecular weight of about 352,000 as follows:

25 4540 parts of polymer are mixed with 449 parts of masterbatch containing 5% of copper phthalocyanine blue pigment in polymer and tumbled for 30 minutes in a small drum tumbler. The blend is then transferred to the extruder hopper dryer and dried 15-18 hours at 160°F. 25

30 The polymer is then extruded through a standard plasticating screw extruder at 0.3 lbs./hr. The extruder has three barrel zones held at 451°F., 446°F. and 481°F. The head containing the pump and filter is held at 445°F. and the spin jet at 535°F. The spin jet has 8 holes with 20 mil diameter capillaries. The filaments extruding from the jet pass through an aqueous quench bath held at 150°F. and are pulled away by a godet assembly rotating at 30.5 fpm to give primary draw down of about 4.8X. From this godet the yarn is drawn by a 35 second godet rotating at 161 fpm through a hot water draw tank six feet long heated to 205°F. to give about a 5.3X draw ratio. The drawn yarn is drawn away from the second godet by a third godet rotating at 250 fpm through a second chamber heated to 310°F. to give an additional draw ratio of about 1.55X. 35

40 The yarn is then separated into the 8 individual filaments and collected on takeup spools as individual monofilaments. At the end of a collection period the monofilaments are wound off onto appropriate size drums and then cut to give strands of the desired length for suture manufacture. The results of tests conducted to determine the properties of these filaments are set forth in Table I, below, in addition to properties of size 1/0, 01 and 02 sutures (Examples 7-9, respectively), prepared by techniques equivalent to those described in 45 Examples 1-6. 45

The flexural fatigue resistance values (cycles to break) reported in Table I are actual values obtained by means of the test procedure described above. The reported values are approximately equal to those which are given by applying the formula.

Flexural Fatigue Resistance = $1.251 \times 10^8 \times D^{-1.77}$ where D is the denier of the test suture.

TABLE I

Filament of Example No.	1	2	3	4	5	6	7	8	9
Filament size (U.S. Pharmacopeie)	2/0	3/0	4/0	5/0	6/0	7/0	1/0	01	02
Filament denier	713	385	256	140	62	36	1041	1448	2088
% Elongation To Break	23	27	29	26	20	24	21	21	24
Static Creep Δ % Elongation	5.4	7.6	6.0	4.7	2.9	2.0	5.9	-	-
Flexural Fatigue Resistance Cycles to break	1100	1500	5000	21,000	84,100	602,000	600	260	450
Young's Modulus 10^8 psi/G.P.D.	$\frac{6.9}{60.4}$	$\frac{6.2}{54.2}$	$\frac{7.6}{65.6}$	$\frac{7.4}{63.7}$	$\frac{9.3}{76.0}$	$\frac{9.3}{75.8}$	$\frac{7.0}{53.9}$	$\frac{5.4}{48.3}$	$\frac{5.7}{48.8}$
Tensile Strength At Break, GPD	5.2	5.3	5.5	6.0	7.0	7.2	4.9	4.5	4.3
Knot Strength, GPD	3.6	4.0	3.9	4.2	5.0	5.0	3.3	3.3	3.0

The corresponding properties of a commercially available isotactic polypropylene suture of identical size are set forth in Table II, below. Again, the flexural fatigue resistance values given are measured values rather than values derived from the previously quoted formula.

TABLE II
(Comparative Characteristics)

Filament size (USP Suture)	1/0	2/0	3/0	4/0	5/0	6/0	7/0
Filament denier	912	657	360	234	153	63	37.8
% Elongation To Break	40	40	33	31	49	45	35
Static Creep, Δ % Elongation	17.2	15.5	15.4	14.1	17.2	13.2	7.5
Flexural Fatigue Resistance Cycles To Break	131	268	885	589	1106	14,500	46,200
Young's Modulus 10 ⁵ psi/G.P.D	3.7/28.9	3.1/26.3	4.7/39.4	4.3/36.9	3.8/29.7	4.2/32.4	4.8/37.7
Tensile Strength At Break GPD	5.0	4.5	5.0	5.0	4.5	4.7	5.6
Knot Strength, GPD	3.5	3.7	3.8	3.9	3.9	4.5	4.7

* Regulated Load.

WHAT WE CLAIM IS:

1. A substantially isotactic polypropylene (as hereinbefore defined) suture having a diameter of from 0.0025 to 0.030 inch and a denier of from 30 to 3000, said suture having the following characteristics:

5	Tensile Strength at Break - gpd	4.3-7.5	5
	Knot Strength - gpd	3.0-5.0	
	Percent Elongation to Break	20.0-30.0	
	Young's Modulus - psi	5.4×10^5 - 9.5×10^5	
10	Flexural Fatigue Resistance (F) (Cycles to break), approximately equal to that given by the formula: $F = 1.251 \times 10^8 \times D^{-1.77}$ where D = suture denier		10
15	Static Creep % Elongation	<8.0	15

2. A polypropylene suture according to Claim 1, in the form of a monofilament.

3. A polypropylene suture according to Claim 1 or Claim 2 which is attached to a surgical needle, said suture and said needle being sterile.

4. A surgical suture package comprising a sterile enclosure and therein a sterile polypropylene suture according to any preceding claim.

5. A method of preparing a suture as defined in Claim 1 which comprises: (a) extruding a substantially isotactic polypropylene (as hereinbefore defined) at a temperature ranging from 425°F to 550°F into a filament; (b) liquid quenching said filament at a temperature ranging from 125°F to 175°F with a simultaneous drawing thereof of 1.0 to 5.0X; (c) passing said quenched and drawn filament through a heating and drawing zone at a temperature of approximately 205°F to impart thereto a 5.0 to an 8.0X draw;

(d) and passing said heated and drawn filament through a second heating and drawing zone at a temperature ranging from 300°F to 450°F to impart thereto a final draw of from 0.95 to 1.6X.

6. A polypropylene suture, according to Claim 1 and substantially as described in any one of the Examples herein.

7. A method of preparing a polypropylene suture as defined in Claim 1, substantially as described in any one of the Examples herein.

8. A polypropylene suture whenever prepared by a method according to Claim 5 or Claim 7.

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